

**TRANSMITTAL AND NOTICE OF APPROVAL OF  
STATE PLAN MATERIAL  
FOR: HEALTH CARE FINANCING ADMINISTRATION**

1. TRANSMITTAL NUMBER: <u>2003</u> — <u>01</u> — <u>    </u>	2. STATE: Florida
3. PROGRAM IDENTIFICATION: TITLE XIX OF THE SOCIAL SECURITY ACT (MEDICAID)	
4. PROPOSED EFFECTIVE DATE January 1, 2003	

TO: REGIONAL ADMINISTRATOR  
HEALTH CARE FINANCING ADMINISTRATION  
DEPARTMENT OF HEALTH AND HUMAN SERVICES

5. TYPE OF PLAN MATERIAL (Check One):

- ☐ NEW STATE PLAN      ☐ AMENDMENT TO BE CONSIDERED AS NEW PLAN      ☒ AMENDMENT

COMPLETE BLOCKS 6 THRU 10 IF THIS IS AN AMENDMENT (Separate Transmittal for each amendment)

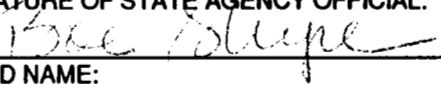
6. FEDERAL STATUTE/REGULATION CITATION: <u>42 CFR 440.120</u>	7. FEDERAL BUDGET IMPACT: a. FFY <u>2003</u> \$ <u>no fiscal impact</u> b. FFY <u>2004</u> \$ <u>no fiscal impact</u>
8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT:  Attachment 3.1-A, pages 46 and 46a Attachment 3.1-B, pages 45 and 45a	9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (If Applicable):  Attachment 3.1-A, pages 46 and 46a Attachment 3.1-B, pages 45 and 45a

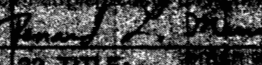
10. SUBJECT OF AMENDMENT:

Prescription Drugs -- Supplemental Rebate Contracts

11. GOVERNOR'S REVIEW (Check One):

- ☐ GOVERNOR'S OFFICE REPORTED NO COMMENT      ☒ OTHER, AS SPECIFIED:  
☐ COMMENTS OF GOVERNOR'S OFFICE ENCLOSED      will be forwarded when received  
☐ NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL

12. SIGNATURE OF STATE AGENCY OFFICIAL: 	16. RETURN TO: Mr. Bob Sharpe Deputy Secretary for Medicaid Agency for Health Care Administration 2727 Mahan Drive, building 3, MS#20 Tallahassee, FL 32308 ATTN: Wendy Johnston
13. TYPED NAME: Bob Sharpe	
14. TITLE: Deputy Secretary for Medicaid	
15. DATE SUBMITTED: March 28, 2003	

FOR REGIONAL OFFICE USE ONLY (Do not fill in until approved by Regional Office)	
17. DATE RECEIVED: March 31, 2003	18. DATE APPROVED: April 1, 2003
PLAN APPROVED - ONE COPY TO BE RETURNED	
19. EFFECTIVE DATE OF APPROVED MATERIAL: January 1, 2003	20. SIGNATURE OF REGIONAL OFFICIAL: 
21. TYPED NAME: Hugh Webster	22. TITLE: Acting Associate Regional Administrator Division of Medicaid, Health Services, and Community Care
23. REMARKS: This amendment to the Medicaid program is a significant change to the program and requires a thorough review of the impact on the program. The Regional Office has reviewed the amendment and has approved it for implementation. The amendment is being implemented on January 1, 2003.	

Covered outpatient drugs are those produced by any manufacturer, which has entered into and complies with an agreement under Section 1927(a) of the Act, which are prescribed for a medically accepted indication. All Medicaid recipients 21 years of age and older will be limited to four brand-name drugs per month. There are no instances in which recipients under the age of 21 have system limitations placed on the number of prescriptions, brand or multi-source, they may receive. Generic drugs, insulin and diabetic supplies, contraceptives, mental health drugs, and anti-retroviral drugs are exempt from these limits. Based on the treatment needs of the Medicaid recipients, the agency may authorize exceptions to the brand-name-drug restriction. These exceptions will be based on prior consultation by the prescriber with the agency or agency contractor. Approved smoking cessation and nicotine replacement products are covered services. As provided by Section 1927(d)(2) of the Act, certain outpatient drugs may be excluded from coverage. Those excluded are DESI drugs; experimental drugs; anorectics (unless prescribed for an indication other than obesity); non-legend drugs (except insulin, aspirin, aluminum and calcium products used as phosphate binders, sodium chloride for specific medical indications, and OTC vaginal antifungals that have previously been legend drugs, when prescribed); and any drugs for which the manufacturer has not entered into rebate agreements with the Department of Health and Human Services, the Veteran's Administration and the Public Health Service. Cough and cold preparations are not covered services for recipients 21 years of age and older. Vitamin and mineral products are covered only under the following circumstances: prenatal vitamins; folic acid as a single entity; fluorinated pediatric vitamins; one vitamin or vitamin/mineral prescription monthly for a dialysis patient; and prescribed ferrous sulfate, gluconate, or fumarate for non-institutionalized patients. (Ferrous sulfate, gluconate, or fumarate is equally available as floor stock to institutionalized patients.) Non-Child Health Check-Up 221 recipients 21 years of age and older cannot receive immunizations, except for influenza and pneumococcal vaccines for institutionalized recipients. Drugs must be prescribed and dispensed in accordance with medically accepted indications for uses and dosages.

Drug Rebate Agreement: The state is in compliance with Section 1927 of the Act. Based on the requirements for Section 1927 of the Act, the state has the following policies for drug rebate agreements:

- The drug file permits coverage of participating manufacturers' drugs.
- Compliance with the reporting requirements for state utilization information and restrictions to coverage.
- A rebate agreement, Version 07/02/03, between the state and a drug manufacturer that is separate from the drug rebate agreements of Section 1927 is authorized by the Centers for Medicare and Medicaid Services. The agreement to be used between the State of Florida and drug manufacturers for supplemental rebates for drugs provided to the Medicaid population has been reviewed and authorized by the Centers for Medicare and Medicaid Services. The state reports rebates from separate agreements to the Secretary for Health and Human Services. The state will remit the federal portion of any cash state supplemental rebates collected.
- Manufacturers are allowed to audit utilization data.
- The unit rebate amount is confidential and cannot be disclosed for purposes other than rebate invoicing and verification.
- Prior authorization programs provide for a 24-hour turn-around on prior authorization from receipt of request, and at least a 72-hour supply in emergency situations.

Amendment 2003-01

Effective 01/01/2003

Supersedes 2001-07

Approved DEC 12 2003

Revised submission \_\_\_\_\_

PREScribed DRUGS:

Attachment 3.1-A

Preferred Drug List with Prior Authorization: In accordance with Florida Statute 409.91195 and pursuant to 42 U.S.C. s1396r-8, there is created a preferred drug list with prior authorization for drugs not included on the preferred drug list. The makeup and appointment authority for the Pharmaceutical and Therapeutic Committee is modified to comply with 42 U.S.C. s1396r-8.

Prior Authorization Requirements:

In accordance with Florida Statute 409.912, prior authorization requirements may be established for certain drug classes, particular drugs, or medically accepted indications for uses and doses.

State Supplemental Rebates:

Florida Statute 409.912 authorizes the state to negotiate supplemental rebates from manufacturers that are in addition to those required by Title XIX of the Social Security Act. The agreement to be used between the State of Florida and drug manufacturers for supplemental rebates for drugs provided to the Medicaid population has been reviewed and authorized by the Centers for Medicare and Medicaid Services.

Prescription Discount Programs: In accordance with Florida Statutes 409.9066, Medicare Prescription Discount Program, and as provider enrollment criteria are developed at the discretion of the Agency, it is required as a condition of Medicaid provider enrollment that Medicaid participating pharmacy providers give price discounts to Medicare recipients who are Florida residents.

Amendment 2003-01  
Effective 01/01/2003  
Supersedes 2001-07  
Approved **DEC 12 2003**  
Revised submission \_\_\_\_\_

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Amendment 2003-01  
Effective 01/01/2003  
Supersedes 2001-07  
Approved **DEC 12 2003**  
Revised submission \_\_\_\_\_

PREScribed DRUGS:

Attachment 3.1-B

Preferred Drug List with Prior Authorization: In accordance with Florida Statute 409.91195 and pursuant to 42 U.S.C. s1396r-8, there is created a preferred drug list with prior authorization for drugs not included on the preferred drug list. The makeup and appointment authority for the Pharmaceutical and Therapeutic Committee is modified to comply with 42 U.S.C. s1396r-8.

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Amendment 2003-01  
Effective 01/01/2003  
Supersedes 2001-07  
Approved **DEC 12 2003**  
Revised submission \_\_\_\_

## **SUPPLEMENTAL REBATE AGREEMENT VERSION 07/02/03**

This Supplemental Rebate Agreement ("Agreement") between the Florida Agency for Health Care Administration ("AHCA"), and [Manufacturer Legal Name] ("Manufacturer"), sets forth the terms and conditions regarding the provision of supplemental rebates on certain of Manufacturer's pharmaceutical products reimbursed by AHCA.

NOW, THEREFORE, the parties to this Agreement agree as follows:

### **1.0 Definitions**

- 1.1. "Florida Medicaid Program" or "Florida Medicaid" shall mean the joint federal and state medical assistance program as established and defined pursuant to Title 42 U.S.C. 1396, et seq., that provides reimbursement for or coverage of prescription drug products to Medicaid Recipients.
- 1.2. "Unit" means drug unit in the lowest identifiable amount (e.g. tablet or capsule for solid dosage forms, milliliter for liquid forms, gram for ointments or creams).
- 1.3. "Preferred Drug List" shall mean the list developed by the P&T Committee and adopted by AHCA pursuant to 2001 Fla. Laws ch. 104 and 42 U.S.C. 1396r-8.
- 1.4. "Fiscal Quarter" shall mean one of the four three-month periods by which the fiscal year is divided, that fiscal year beginning July 1 and ending on the following June 30.
- 1.5. "Medicaid Recipient" shall mean any person enrolled in the Florida Medicaid Program and eligible to receive prescription drug benefits.
- 1.6. "Average Manufacturer Price" or "AMP" shall mean the Average Manufacturer Price as set forth in 42 U.S.C. §1396r-8, as such may be amended from time to time.
- 1.7. "Best Price" shall mean Best Price as set forth in 42 U.S.C. §1396r-8, as such may be amended from time to time, excluding State Supplemental Rebate amounts.
- 1.8. "National Rebate" shall mean any discount provided by a manufacturer pursuant to 42 U.S.C. 1396r-8.
- 1.9. "Product" shall mean any prescription drug product listed in Attachment A.

- 1.10. "Pharmacy" shall mean a facility licensed in accordance with Chapters 465, Florida Statutes, and 64B, Florida Administrative Code, to dispense legend drugs, and enrolled as a Florida Medicaid provider.
- 1.11. "P&T Committee" or "Pharmacy & Therapeutics Committee" shall mean the committee of health care professionals and other individuals constituted pursuant to 2001 Fla. Laws ch. 104 and 42 U.S.C. 1396r-8 for the purpose of developing a Preferred Drug List for the Florida Medicaid Program.
- 1.12. "State Supplemental Rebate" shall mean any cash rebate as defined by 2001 Fla. Laws ch. 104 that offsets a Florida Medicaid expenditure and that supplements CMS National Rebate.
- 1.13. "Wholesale Acquisition Cost" or "WAC" shall mean the published list price Manufacturer charges its authorized wholesalers for each NDC of a Product as of the last day of the fiscal quarter.
- 1.14. "CMS" shall mean the Center for Medicare and Medicaid Services (formerly known as the Health Care Financing Administration) of the US Department of Health and Human Services, or any successor or renamed agency carrying out the functions and duties heretofore carried out by such office.
- 1.15. "New Product" shall mean any pharmaceutical product of Manufacturer that may be launched or otherwise become available from Manufacturer after the date of this Agreement.

## **2.0 AHCA Obligations**

- 2.1. Covered Benefit. AHCA shall provide or arrange for the provision of pharmacy services to Florida Medicaid Recipients.
- 2.2. Network. AHCA or its designee shall maintain provider agreements with Pharmacies to dispense pharmaceutical products to Medicaid Recipients under certain terms and conditions.
- 2.3. Preferred Drug List. AHCA shall adopt and maintain a Preferred Drug List.
  - 2.3.1. Preferred Drug List Documentation and Publication. AHCA shall publish the Preferred Drug List on the AHCA website within sixty (60) days after execution of this Agreement and shall update the website quarterly or after each therapeutic class review by the P&T Committee.

- 2.3.2. P&T Committee. AHCA shall maintain, in accordance with 2001 Fla. Laws ch. 104, a P&T Committee that shall review and recommend pharmaceutical products for inclusion on the Preferred Drug List.
- 2.3.3. Notice of Preferred Drug List Review. Beginning August 1, 2001, AHCA or its designee shall notify Manufacturer of any scheduled review of a Product or competing Product and shall provide Manufacturer the opportunity to present information on the Product's merits for inclusion in the Preferred Drug List.
- 2.3.4. Preferred Drug List Distribution. AHCA or its designees shall arrange for print distribution of the Florida Preferred Drug List to Florida Medicaid provider physicians and Pharmacies on or by October 1, 2002, and annually thereafter.
- 2.3.5. Addition of New Products to Preferred Drug List. Manufacturer shall notify AHCA of any New Product and , subject to Section 3.1, the State Supplemental Rebate available on such New Product. Provided that the amount of the State Supplemental Rebate available on such New Product is acceptable to AHCA, AHCA shall recommend to the P&T Committee that such New Product be added to the Preferred Drug List, and upon such addition such New Product shall be deemed a Product for all purposes under this Agreement. No Product, including any New Product on the Preferred Drug List shall be discouraged or disadvantaged in any way relative to any other brand name pharmaceutical products on or off the Preferred Drug List. AHCA shall use the same process for presenting Manufacturer's New Products to the P&T Committee as that used for any other brand name manufacturer.
- 2.3.6. Availability of Non-Preferred Drug List Drugs. Non-Preferred Drug List drugs are available through the formal Prior Authorization Process.
- 2.4. Invoicing. AHCA shall invoice State Supplemental Rebates separately from National Rebates, using the format set forth in Attachment B. AHCA shall submit the State Supplemental Rebate invoice to Manufacturer within sixty (60) days after the fiscal quarter in which the Product was paid for by AHCA. Any amended invoice shall be submitted by AHCA within twelve (12) months after the fiscal quarter in which the Product was paid for by AHCA. AHCA shall not provide to Manufacturer any patient identifiable information or protected health information or any other information the disclosure of which is prohibited or regulated by laws or regulations governing confidentiality of medical or other information.

- 2.5. Fraud & Abuse. It is AHCA's belief that the business arrangement contemplated by this Agreement is not subject to the provisions of 42 U.S.C. 1320a-7b(b) prohibiting illegal remunerations. In addition, to the extent that AHCA has any reason to believe that the arrangement described in this Agreement does not meet the regulatory parameters of the discount safe harbor described above, AHCA shall immediately notify Manufacturer.
- 2.6. Competitive Circumstances. AHCA represents and warrants that the State Supplemental Rebates provided herein by Manufacturer have been negotiated under circumstances which render the net prices of the Products competitive with the net prices of pharmaceutical products that are used to treat the same conditions.

### **3.0 Manufacturer Obligations**

- 3.1. State Supplemental Rebate Payment. Manufacturer agrees to provide a State Supplemental Rebate to AHCA for each of its Products listed on Attachment A that is dispensed to Medicaid Recipients by Pharmacies for each fiscal quarter that each Product is included in the Preferred Drug List. Manufacturer shall pay to AHCA the State Supplemental Rebate amount in accordance with the formula set forth in Attachment C. Nothing in this Agreement shall be construed to relieve Manufacturer from its obligation to pay National Rebates under contracts, if any, with CMS for utilization by Florida Medicaid Recipients. At no time shall the National Rebate amount plus the State Supplemental Rebate amount for any given Product fall under 25.1 percent of the AMP of that Product. AHCA shall report and remit State Supplemental Rebate payments made under this Agreement to CMS as required under its approved state plan and applicable laws and regulations.
- 3.1.1. Payment Timeframe. Manufacturer shall pay to AHCA the State Supplemental Rebate amount to which AHCA is entitled in accordance with the formula set forth in Attachment C, within thirty-eight (38) days of receipt of AHCA's report described in Attachment B of this Agreement and AHCA's National Rebate Invoice for the same Fiscal Quarter. Manufacturer's failure to remit the State Supplemental Rebate amount in a timely manner may result in the removal of the relevant Product or Products from the Preferred Drug List, pursuant to the application of the dispute resolution process set forth in Section 3.1.2. of this Agreement.
- 3.1.2. Incomplete Submission: Manufacturer shall have no obligation for claims that are not submitted as part of an invoice in accordance with Section 2.4 of this Agreement. Manufacturer shall notify AHCA or its designee of any incomplete submission it may become aware

of within thirty- eight (38) days of Manufacturer's receipt of such submission pursuant to Section 2.4 and AHCA's National Rebate Invoice for the same Fiscal Quarter.

3.1.3. Over/Underpayment: If either party discovers an error in the payment of State Supplemental Rebates by Manufacturer, it shall notify the other of such error. The parties shall attempt to reconcile all differences through discussion and negotiation; if that attempt fails, the parties will resolve their dispute in accordance with generally applicable procedures followed by AHCA or CMS in disputes concerning National Rebates. Manufacturer shall deduct any overpayment from subsequent State Supplemental Rebates payable under this Agreement. In the event that no subsequent State Supplemental Rebates are payable, AHCA will refund any such overpayment to Manufacturer within thirty (30) days of its acknowledgement of the overpayment. Manufacturer will remit any underpayment to AHCA by adding the underpayment to the subsequent Supplemental Rebate payable under this Agreement. In the event that no subsequent State Supplemental Rebates are payable, Manufacturer will pay the amount of any such underpayment to AHCA within thirty (30) days of Manufacturer's acknowledgement of such underpayment.

3.1.4. Product Utilization Eligible for Rebate: Product utilization under the Preferred Drug List shall only be eligible for State Supplemental Rebates pursuant to Attachment C only if and when it meets all of the following conditions:

3.1.4.1. Own Use: The Product shall have been dispensed and used in connection with this Agreement only for Medicaid Recipients and only for their own use.

3.1.4.2. Late Submission: Utilization information for such Product has been provided within one hundred eighty (180) days after the fiscal quarter in which the Product was paid for by AHCA.

3.1.4.3. Electronically Adjudicated Claims: The claim for the Product is electronically adjudicated by AHCA at the time the Product is dispensed by a Pharmacy.

3.2. Discretion to Market. Nothing in this Agreement shall be construed to prohibit Manufacturer from discontinuing production, marketing or distribution of any Product or from transferring or licensing any Product to a third party. It is understood that Manufacturer is liable for the payment of State Supplemental Rebates only on Products (as identified by their 9-